

N THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: GARAVANI ALBERTO, RAPAPORT IRINA

Serial No. 10/104,410

Filed: March 21, 2002

Title: "CICATRIZANT HYDROCOLLOIDAL PATCH CONTAINING

HYALURONIC ACID AND CHONDROITIN SULFATE"

DECLARATION UNDER CFR1.132

I, IRINA RAPAPORT, declare what follows:

- 1. I am a Swiss citizen residing at 6821 Rovio, Switzerland,
- 2. I am familiar with the English language.
- 3. I further declare that:

A) EDUCATION

In 1979 I graduated in Chemical Engineering at the Federal Polytechnic School of Lausanne, Switzerland and in 1987 I graduated in Chemistry (Ph.D.) at the University of Lausanne, Switzerland.

B) JOB EXPERIENCES

From 1988 up to today I have been working at IBSA - Institut Biochimique SA in 6915 Pambio-Noranco (Switzerland) as Head of the R&D Analytical Laboratory (from 1988 to 2002) and as Regulatory Affairs Manager (since 2003).

I am also a co-inventor of the following US Patents: 5,206,262 / 6,162,905 / 6,592,891 / 6,379,695.

C) EXPERIMENTAL SECTION

I declare that during the period in which the experiments reported in the Patent were performed, I was involved in the hydrocolloidal patch development project as Head of the R&D Analytical Laboratory. The experiments reported in the Patent were carried out under the responsibility of the R&D Clinical Dept., which acquainted me with the results.

I further declare that I have read and I am familiar with the Office Action dated December 19, 2006 concerning the Patent Application at issue. I learned from reading it that the Examiner is of the view that my invention as it is presently claimed is deemed obvious by the USPTO in view of EP 302 536 and US 5,631,011 and the article of Fialkova.

I do not agree with such opinion. When we tested our first patches, the concentrations of sodium hyaluronate and CS were quite high, 2% and 5%. While the cicatrizant effect was obtained, it was not in compliance with our goals. In the Fialkova article, the concentration of the sole CS in the aqueous solution was even higher, in particular 10%. Even though solutions and plasters cannot be directly compared, we would have concluded from the Fialkova article that the concentration which we employed in the first test patches were too low.

It was therefore a complete surprise to us and totally unexpected that with respect to the further test plasters which we prepared, those plasters with the reduced concentrations led to the best results. 4. I finally declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that such wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardise the validity of the applications or any patents or re-examination certificate issued thereon.

Date: June 22th, 2007